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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,332	11/21/2000	Narmada Shenoy	038602-1060	9626

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EXAMINER
JONES, DWAYNE C

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/716,332	SHENOY ET AL.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *the election response of 28 MAR 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1-84 are pending.

2. Claims 1-84 are rejected.

Election/Restrictions

3. The restriction requirement of January 31, 2002 between Groups I and II is hereby removed; however, the election of species requirement is maintained. The elected species of 3-[2,4-dimethyl-5-(2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-1H-pyrrol-3-yl]propionic acid was found to be rendered obvious over the prior art reference of Tang et al. U.S. Patent No. 5,792,783, (see below in paragraphs No 11).

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 78 and 80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a protein kinase related disorder, does not reasonably provide enablement for preventing a protein kinase related disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant claims and specification are directed to preventing a protein kinase related disorder, protein kinase disorder embrace cell proliferative disorders, such as cancers, blood vessel proliferative disorders, arthritis, fibrotic disorders, (see column 8, lines 41-63 and columns 13 and 14 of Tang et al. U.S. Patent No. 5,792,783). Moreover, the cancer therapy art remains highly unpredictable, and no example exists for efficacy of a single product against tumors generally. Specifically, Internal Medicine, 4th Edition, Editor-in-Chief Jay Stein, Chapters 71-72, pages 699-715, teaches that the various types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Based on this state of the art, an ionizable substituted indolinone would expected to be effective against the treatment of cancer, but not for the prevention of cancer. Since the instantly claimed compounds are structurally related to the compounds of Tang et al. U.S. Patent No. 5,792,78, one skilled in the art would expect the compounds used in the instant claims to be effective for the treatment, rather than the prevention of the cancer. Applicants have provided no guidance or working examples teaching one skilled in the art how to determine which of the countless products used in the instant claims would be effective to prevent cancer. As evidenced by the references noted above, one would not expect

the instantly claimed compounds to be effective against the prevention of cancer. Therefore, based on the unpredictable nature of the invention and state of the prior art, the lack of working examples, and the extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tang et al. U.S. Patent No. 5,792,783. Tang et al. teach of compounds, in particular those of formula (III), which modulate, regulate and/or inhibit tyrosine kinases and its signal transduction, (as cited from column 1, lines 9-17 and from column 10, line 31 to column 11, line 8). Tang et al. further teach of pharmaceutical formulations and various routes of administration, including parenteral and oral administrations, (column 15 and 16).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al. U.S. Patent No. 5,792,783. Tang et al. teach of compounds, in particular those of formula (III), which modulate, regulate and/or inhibit tyrosine kinases and its signal transduction, (as cited from column 1, lines 9-17 and from column 10, line 31 to column 11, line 8). For these reasons, the compounds of Tang et al. are effective in treating various disorders related to unregulated tyrosine kinase signal transduction, which includes cell proliferative disorders, such as cancers, blood vessel proliferative disorders, arthritis, fibrotic disorders, (see column 8, lines 41-63 and columns 13 and 14). The claims differ from the reference by reciting a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. *In re Susi*, 440 F.2d 442, 445, 169 USPQ 423, 425

(CCPA 1971), followed by the Federal Circuit in *Merk & Co. vs. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
June 5, 2002